

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND
IRBESARTAN PRODUCTS LIABILITY
LITIGATION

This document relates to:
All Actions

MDL No. 19-2875 (RBK/KW)

Honorable Robert Kugler
Magistrate Karen Williams
Special Master Thomas Vanaskie

**PLAINTIFFS' REPLY IN SUPPORT
OF THEIR MOTION TO STRIKE
AND SUPPRESS ALL OF
AUROBINDO'S DEFENSES**

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In response to Plaintiffs' Motion, Aurobindo makes no apology for its behavior. Instead, Aurobindo defends its misstatements by alleging neither its statements on the record, nor its certifications served on Plaintiffs, should have been taken at face value. In other words, Aurobindo's statements were not to be believed in the first place. Aurobindo further suggests Plaintiffs have suffered no prejudice because they can simply take every deposition twice.

Aurobindo's minimization of its actions makes its own case for why these sanctions are warranted. Aurobindo's positions that it can say one thing and do another, that its failure to produce over 80% of relevant documents is not prejudicial to Plaintiffs, and that court orders can be disregarded without consequences, are unsupportable. Aurobindo's repeated acts in bad faith cannot go unchecked.

Plaintiffs are now less than two months away from their deadline to produce expert reports, and the prejudice to Plaintiffs continues to pile up on a daily basis as Plaintiffs are forced to take more depositions based on an incomplete record.

I. AUROBINDO'S ACTIONS BLATANTLY CONTRADICT ITS SUGARCOATED VERSION OF EVENTS

Aurobindo attempts to distinguish its misrepresentations, but the record speaks for itself:

A. Aurobindo Defends its Misstatements by Arguing Those Statements Were Not to be Taken at Face Value When They Were Made

Aurobindo's response to many misstatements made to the Court seems to be that those statements should not have been taken seriously when they were made. *See* Defs.' Mem., pp. 21-25.

1. Aurobindo falsely stated it had collected data from all US custodians in June 2020.

This facially absurd approach begins with Aurobindo's defense of its statement that it had loaded the data for all of its 15 custodians in July 2020. *See* Ex. C, 06/17/2020 Hrg. Tr. 38:19-22 ("We have run -- we have collected all of our custodial files. They have been uploaded into our vendors system. We started reviewing."). Aurobindo's response, that this did not mean no new data could be collected in the future, misses the point entirely. Aurobindo's belated production from US custodians did not

consist of information from new custodians or emails that were sent in the period between the initial collection and any collection that may have happened later. This was information known to and accessible by Aurobindo since this case began.

As shown in Figures 1-4 in Plaintiff's opening brief, the data produced late by Aurobindo should have been part of the original data collection. Because the documents produced late were not created recently, there are only two explanations for what happened: (1) Aurobindo had collected all of the documents and knowingly withheld the vast majority of them, or (2) Aurobindo falsely stated to the Court in June 2020 that it had collected "all of our custodial files." Neither is acceptable.

2. Aurobindo falsely stated that it had produced everything it had in December 2020

In defense of its misstatement to the Court that Aurobindo had produced "everything we have" at the December 9, 2020 status conference, Aurobindo's only response is that neither Plaintiffs nor the Court should have construed the statement as a "representation of finality." Defs.' Mem. p. 23. It is difficult to fathom how this statement could be interpreted differently. Indeed, the very reason Plaintiffs and the Court asked each defendant if their production was substantially complete was for the express purpose of giving Plaintiffs sufficient time to review documents in advance of depositions. Ex. D., pp. 14:7-15:15.

3. Aurobindo provided a false certification that it had completed its production of standard operating procedures

Aurobindo does not dispute that it has produced additional standard operating procedures following its certification that this process was complete. *See* Defs.' Mem., p. 24. Aurobindo attempts to wiggle out of the certification it served (Ex. O) by pointing to its reservation to supplement. Plaintiffs would not have protested if a few SOPs trickled in after the certification was served, but this is not what happened. After Aurobindo served its certification on March 4, 2021, it subsequently

produced more than 150 SOPs from the US entities¹ and approximately 1,450 SOPs from APL.² Aurobindo's certification was untrue.

4. *Aurobindo again misrepresented the completeness of its production at the March 12, 2021 conference with the Court*

Plaintiffs repeatedly questioned Aurobindo on its production of noncustodial documents. In response, at the March 24, 2021 status conference Aurobindo stated,

I did not refuse to search any other of the other drives that she mentioned. I'm still discussing that with my client. *It's my understanding that all of the proper noncustodial data sources were searched and produced* from, I'm working on going back to my client and communicating Ms. Goldenberg's concerns to them, and I offered to meet and confer with her about this later this week.

Ex. H, 03/24/2021 Hrg. Tr., p. 14:8-14.

However, APL made no productions of shared drive data until April 28, 2021. To date, according to the production log, APL has made two productions that contain shared drive data. A search within the bates ranges specified in the log reveals that out of the 57,809 documents produced in this bates range, only 823 are from noncustodial sources (and presumably from shared drives).³ Indeed, at the May 3, 2021 status conference, Aurobindo disclosed that “a large amount of data” from shared drives remains to be produced, demonstrating that Aurobindo's statement at the March 24, 2021 conference was not true. Ex. FF, 05/03/21 Hrg. Tr. p. 48:12-19.

5. *Aurobindo's Misrepresentations about its Ability to Transfer Data via FTP Delayed its Production of Documents During a Critical Time and Greatly Prejudiced Plaintiffs' Ability to Prepare for and Take Meaningful Depositions*

Aurobindo characterizes its misrepresentation about its ability to transmit data via FTP as “a minor misunderstanding.” Defs.' Mem., p. 22. The company also attempts to wriggle out of its statements

¹ See Goldenberg Dec. ¶ 18 (explaining search methodology employed to reach this number).

² See Goldenberg Dec. ¶ 19 (explaining search methodology employed to reach this number).

³ See Goldenberg Dec. ¶ 20 (explaining search methodology employed to reach this number).

by alleging it never made any affirmative representations about the company's ability to transmit documents. Defs.' Mem., pp. 21-22. **This is not true:**

"And I understand Ms. Marlene -- Ms. Goldenberg said that, you know, she's not familiar with data having to be put on a hard drive. This data was very large. It could not be transferred via an FTP link. We had to put it on these hard drives; they had to ship them overseas."

...

"And so it's my understanding that this is way too large to be transferred via an FTP."

Ex. G, 03/12/2021 Hrg. Tr. 74:9-13, 75:14-16.

Only when pressed after these exchanges did Aurobindo agree to check to see if a transfer via FTP could be accomplished. *Id.*, p. 76:19-24. However, even after agreeing to look into the feasibility of an FTP transfer, Aurobindo dug its feet in and once again stated FTP transfers of data were not possible: "It's my understanding from Aurobindo that they have been unable transfer the data via FTP." Ex. H, 03/24/2021 Hrg. Tr., p. 20:4-5. Aurobindo only executed its FTP transfer after being ordered to do so by the Court. Adding to the disturbing nature of this misrepresentation are the documents Plaintiffs have now uncovered in Aurobindo's recent productions, proving Aurobindo has been executing FTP transfers of documents as far back as 2012 (Ex. BB), that the company has long understood how to send large files via FTP (Ex. CC), and that the company has established internal and external FTP sites for domestic and international use (Exs. DD, EE).

By March 31, 2021, only after the Court ordered the transfer of documents via FTP, Aurobindo transmitted the documents it could and should have sent shortly after the Court ordered the production of the custodial files at issue on February 24, 2021. *See* Ex. F, pp. 44:19-45:2. Instead, Aurobindo dragged its feet during the critical time when Plaintiffs were preparing for depositions and did not begin to produce the vast majority of its documents from Aurobindo Pharma Ltd. until depositions were already underway. *See* Ex. GG.

In fact, Aurobindo Pharma Ltd. made absolutely no effort to respond to Plaintiffs' Rule 34 requests. The parent company produced *two documents* in response to these requests through the production deadline. No shared drive data from APL were produced until two weeks ago. Ex. GG.

II. THE PREJUDICE ON PLAINTIFFS HAS ONLY COMPOUNDED SINCE PLAINTIFFS FILED THEIR MOTION

Aurobindo boldly suggests that Plaintiffs have suffered no prejudice because the company is willing to make all of its witnesses available again. In other words, Aurobindo expects Plaintiffs to take every deposition twice to compensate for Aurobindo's failure to timely disclose mountains of evidence. Aurobindo conveniently glosses over the fact that this would require double the effort, double the expense, months of extra time, and will not bring back destroyed documents.

But most importantly, Aurobindo overlooks the fact that this MDL is all set to move at the same pace, with all expert reports being due on the same date. There is also a single deadline for *Daubert* motions, *Daubert* and hearings, and motions for class certification. Aurobindo's proposal not only requires all depositions of its witnesses to be taken again- it requires a second round of expert reports, a second round of *Daubert* motions and hearings, a second round of motions for class certification, and potentially separate deadlines for liability discovery, summary judgment, and trials involving plaintiffs who took Aurobindo's valsartan-containing drugs.

This unitary schedule is critically important, because many plaintiffs who assert personal injury claims have "mixed-use" cases. In other words, many plaintiffs took VCDs manufactured by multiple defendants (e.g., Aurobindo and ZHP). Similarly, as to class certification, Defendants themselves have insisted previously that all claims against all Defendants proceed in lockstep, not in a staggered fashion. If Aurobindo's case falls behind, that has a domino effect on the entire MDL. A second track for Aurobindo will consume a tremendous amount of the Court's time and resources.

A. The US Auro Entities Have Continued to Dump Previously Withheld Documents

Even beyond the absurdity of Aurobindo's proposal for remedying the prejudice Plaintiffs have suffered, Aurobindo continues to dump documents on Plaintiffs. Since Plaintiffs' motion was filed, the US Aurobindo entities have produced more than 6,500 documents. This is an approximate 50% increase from the 12,428 documents the US entities had produced by the production deadline. *See* Ex. GG. Aurobindo points to a variety of excuses (i.e., COVID-19, international clients, and language barriers) for failing to do the same things that every other manufacturer defendant in this case managed to accomplish in the same amount of time. However, there are no language barriers or international client issues with a US entity, and the Court already granted all parties an extension to account for any COVID-19-related delays. *See* ECF 416 (text order).

Similarly, between the end of Core Discovery and November 30, 2021, Aurobindo Pharma Ltd. Produced *eight pages* of documents (two organizational charts). *See* Ex. GG. There is simply no world in which this production is the result of a diligent search.

B. Aurobindo Has Not Been Cooperative

1. Aurobindo Withheld Documents until the Last Minute

Aurobindo reasons that sanctions are inappropriate because it allegedly has been cooperative and has acted in good faith in remedying production deficiencies. Its productions tell a different story. Aurobindo blamed its failure to produce over 80% of its US document production on "an internal miscommunication within the IT team at Aurobindo" that the company allegedly learned of in February. Defs.' Mem., p. 7. Had this truly been the case, Plaintiffs would have expected there to be a communication to that effect from Aurobindo at some point before Aurobindo put this in its brief. That never happened. Had this truly been the case, Plaintiffs also would have expected Aurobindo to promptly begin producing these newly discovered documents. That also did not happen. *See* Ex. GG.

Aurobindo made no custodial productions from the US entity between November 25, 2020 and March 18, 2021 (the night before the first deposition). Instead, Aurobindo strategically made productions of additional documents on the eve of each deposition taken to date. *See* Ex. GG. As shown in Aurobindo’s production index, these productions contained almost exclusively documents relating to the individual about to be deposed. *See id.*

By the time Dr. Rao’s⁴ deposition was imminent, Aurobindo’s offer to push the deposition back was unhelpful. Plaintiffs are now being forced to choose between obtaining a record based upon an incomplete production (and having at least some testimony to provide to their experts) or pushing the depositions back far enough to a point where Plaintiffs had been afforded the opportunity to review documents but also to a date on which it would be too late for Plaintiffs’ experts to use that testimony for their reports. *See generally*, Ex. HH, Rao Dep. Tr. Neither option is viable. These are choices parties should not have to make. The very reason scheduling orders and production deadlines were carefully set out by the Court was to prevent precisely this type of problem.

2. Aurobindo Blatantly Ignored its Obligation to Respond to Discovery Requests

Aurobindo acknowledges that Plaintiffs began questioning the size of Aurobindo’s production once the November deadline passed. *See* Defs.’ Mem., p. 7 (“Plaintiffs emailed defense counsel, raising purported deficiencies in the document productions by the U.S. entities but did not identify any documents that were missing from the productions.”). Plaintiffs should not be expected to know that Aurobindo had yet to produce 83% of its documents, nor should Plaintiffs be expected to have to tell Aurobindo to produce documents from custodial files it had already been ordered to produce or from

⁴ Dr. Rao is the Chief Quality Officer at APL, Unit XI, which manufactured finished-dose VCDs.

relevant, noncustodial sources. After all, Aurobindo had already represented to the Court all documents had already been produced. Ex. D, 12/09/2020 Hrg. Tr. p. 21:3-4.⁵

3. Aurobindo Improperly Withheld Documents on its Privilege Log

Aurobindo improperly designated approximately 3,500 documents as privileged and again seeks credit for “agree[ing] to produce some of these documents...” Defs.’ Mem., p. 10. In reality, the vast majority of these documents were improperly designated. Only after Plaintiffs included an insert in their agenda letter did Aurobindo agree to produce the vast majority of them. Rather than admitting that it withheld relevant documents, Aurobindo now seeks credit from the Court for belatedly (and after multiple depositions had already been taken) agreeing to produce some of the improperly withheld documents that should have been produced in the first place.

III. AUROBINDO’S RESPONSE CONFIRMS IT SPOILIATED EVIDENCE

A. Aurobindo Destroyed Documents by Deleting Data from Laptops

Aurobindo disclosed *for the first time ever* in its opposition that data on the computers of two of its custodians was deleted, and that it “has endeavored” to obtain documents from backup tapes. Defs.’ Mem., p. 15. This, coupled with Aurobindo’s recently produced document retention policy and a closer look at these custodial files, demonstrates that not all was recovered.

APL’s Corporate Email Policy provides that only employees at the Director level have unlimited space in their inboxes. Ex. II, p. 2. The policy further provides that emails are backed up to a server or backup tape, but these tapes are retained for only one year. *Id.*, p. 4. When a user’s inbox reaches 90%, the company policy requires a user to archive emails in a personal folder on their PC, and

⁵ Defendants cite to the Sedona Principles for the proposition that parties are in the best position to know their own documents. The Sedona Conference Commentary on Legal Holds also expressly advises parties to collect custodial data from laptops. *See* Ex. JJ, p. 396. Aurobindo’s attorneys have also published articles on the importance of issuing litigation holds. *See* <https://www.cwlaw.com/journal/new-federal-electronic-discovery-rules>.

specifically directs users to “carry out frequent deletion of the mails from mail servers, to avoid getting the mail alerts and to remain within the quota provided.” *Id.* Emails taken off the network (i.e., via archival or deletion) for more than one year are not retained. Without a litigation hold in place, emails are not preserved. Thus, for any custodian who did not receive a litigation hold, any deleted or archived emails older than one year would have been deleted permanently.

Accounts for former employees are also subject to deletion and will not be backed up for longer than one year. *See id.*, pp. 4-5. This explains the lack of emails produced for the two custodians whose computers were erased, MV Subba Raju and A Srinivasa Reddy. A search of each custodian’s emails reveals gaping holes in the productions, spanning months at a time. *See* Goldenberg Dec. ¶¶ 21, 22 (showing timelines of emails produced).

Despite the fact that these custodians left the company in March 2019 and July 2019, respectively (*see* Exs. KK and LL) (i.e., almost a year after this litigation commenced in the summer of 2018), both email accounts apparently continued to receive relevant emails and be copied on responsive correspondence, including CAPA updates, analyses of the source and extent of the NDEA contamination, and audits conducted of Aurobindo’s facilities relating directly to valsartan which revealed major cGMP concerns. *See, e.g.*, Exs. MM, NN, and OO. Any emails were sent during these large gaps in time are not be available to Plaintiffs due to the destruction of this information. This is far from speculation— the data speaks for itself. Documents have been lost.

B. Other Aurobindo Pharma Ltd. Custodial Files Are Also Missing Emails

While Aurobindo disclosed that two custodial files were not properly preserved, there are several others with gaping holes in the available email history. Most notable is the custodial file of Buggala Nagaraju, one of the custodians selected by Aurobindo on the Lantech contamination issues. When Aurobindo designated Mr. Nagaraju, Plaintiffs questioned this choice, as his name rarely appeared in

documents. Ex. G, 03/12/21 Hrg. Tr. p. 83:15-25. Aurobindo reassured the Court, “Those are the appropriate people.” *Id.*, p. 84:15. *See also*, Ex. PP (confirming the same).

At the May 3, 2021 status conference, Aurobindo then informed the Court that it had finished its custodial production for all APL custodians. Ex. FF, 05/03/21 Hrg. Tr. pp. 48:22-49:1. In spite of the fact that Mr. Nagaraju has worked at Aurobindo for five years and was apparently one of the individuals closest to the Lantech contamination issues, *he has only 31 emails in his custodial file*. Goldenberg Dec., ¶ 23. Taking Aurobindo at its word that Mr. Nagajaru was intimately involved with one of the most important issues in the case, and also noting that he did not receive a litigation hold (Ex. Y), the only logical conclusion is that his documents were destroyed.⁶

C. Aurobindo’s Intentional Failure to Issue Litigation Holds and Properly Collect ESI Resulted in Spoliation of Evidence

In defending its litigation holds (or lack thereof), Aurobindo chose its words carefully. It wrote that it “took prompt action to collect *email data* from all custodians.” Defs.’ Mem., p. 14 (emphasis added). What it did not collect was data from custodians’ computers, cell phones, hard copy documents, or any other source of information. Aurobindo suggests that data housed elsewhere is likely duplicative, but this is not so.

The most obvious types of documents that are not kept in a custodian’s email are draft (or final) Word, Excel, and PowerPoint documents. *See* Ex. W (explaining that Aurobindo custodians utilized these programs). Not only are these documents kept elsewhere (locally on a computer and thus not subject to a network backup) or on a shared drive, but the lack of a litigation hold means they were not preserved.

⁶ To the extent Aurobindo responds to this by supplementing this production, it would have made yet another misstatement to the Court on May 3, 2021 by informing the Court that it had “produced all responsive data to the plaintiffs as of last night.” Ex. FF, 05/03/21 Hrg. Tr. p. 48:22-49:1.

IV. AUROBINDO HAS FAILED TO CITE TO A SINGLE CASE THAT SUPPORTS LESSER REMEDIES

Aurobindo relies upon case law that shields only those parties who acted unintentionally or who did not exhibit a pattern of sanctionable conduct. *See, e.g., Bensel v. Allied Pilots Ass'n*, 263 F.R.D. 150, 153 (D.N.J. 2009) (no sanctions warranted in absence of bad faith); *Kavanagh v. Refac Optical Grp.*, No. CV 15-4886 (JHR/JS), 2017 WL 6395848, at *3 (D.N.J. Dec. 14, 2017) (no sanctions for spoliation absent showing of lost evidence). Instead, the cases relied upon by Aurobindo all support the notion that the punishment must fit the crime. *See, e.g., Poulis v. State Farm Fire & Cas. Co.*, 747 F.2d 863 (3d Cir. 1984). Aurobindo, on the other hand, has made multiple misrepresentations to the Court, withheld and continues to withhold relevant evidence, and failed to preserve and consequently spoliated swaths of evidence. The *Wachtel* findings apply equally here:

Defendants continue to ignore the Court's rulings over and over again. Defendants' persistent pattern of delay, defiance of Court Orders, evasive responses to Plaintiffs' discovery requests, and lack of candor have resulted in crushing prejudice to Plaintiffs in the form of forgetful witnesses and extraordinary expenditures of time, effort, and money.

Wachtel v. Health Net, Inc., 239 F.R.D. 81, 99 (D.N.J. 2006).

V. CONCLUSION

For all of these reasons, Plaintiffs respectfully request Plaintiffs' motion be granted.

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Respectfully Submitted,

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